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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/738,454

12/16/2003

K. Dane Witttrup

97-99E

8855

23713

7590

04/22/2005

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EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/738,454

Applicant(s)

WITTRUP ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-97 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-97 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

RD

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 94-95, drawn to methods for displaying or selecting proteins for displayability on a yeast cell surface, classified in class 435, subclass 7.1.
- II. Claims 6-9, 22-29, drawn to a library comprising a plurality of different polypeptides displayed on yeast cells and yeast cells displaying a fusion protein having an amino acid sequence consisting of a ligand binding sequence joined at its N-terminus to the C terminus of a yeast cell wall protein such as agglutinin subunit Aga2p, classified in class 435, subclass 254.2.
- III. Claims 10-21, drawn to fusion proteins displayed on a yeast cell surface, classified in class 530, subclass 350.
- IV. Claims 30-32, 38-69, drawn to methods of producing a yeast cell displayed variant ligand binding protein with enhanced binding properties relative to a wild-type of said ligand binding protein and kits for producing yeast cells displaying variant ligand binding proteins with enhanced binding properties and gene expression cassettes and vectors, classified in class 435, subclass 471.
- V. Claim 33, drawn to a variant T cell product, classified in class 530, subclass 350.

- VI. Claim 34, 36, drawn to processes for developing mutant polypeptides exhibiting more favorable (enhanced) binding of a ligand relative to the binding characteristics of a wild-type of said polypeptide for said ligand, classified in class 435, subclass 6.
- VII. Claims 35 and 37, drawn to DNA intermediate products coding for mutated polypeptides having enhanced binding activities for ligands, classified in class 536, subclass 23.1.
- VIII. Claims 70-74, drawn to a method for using high affinity TCRs to identify ligands, classified in class 435, subclass 7.1.
- IX. Claims 75-76, drawn to methods for using high affinity TCRs to treat disease or block autoimmune destruction of cells, classified in class 514, subclass 2.
- X. Claims 77-79, 82 and 92-93, drawn to soluble high affinity TCRs or libraries of said TCRs displayed on yeast cells or pharmaceutical compositions comprising said TCRs, classified in class 424, subclass 185.1.
- XI. Claims 81, 88-90, drawn to DNA sequences encoding soluble high affinity TCRs, classified in class 536, subclass 23.5.
- XII. Claims 83-85, drawn to a method for cloning a gene from a high affinity TCR mutant, classified in class 435, subclass 455.
- XIII. Claim 86, drawn to T cells, classified in class 435, subclass 372.3.

- XIV. Claim 91, drawn to a method for selecting proteins for displayability on yeast cell surfaces, classified in class 435, subclass 7.31.
- XV. Claim 96, drawn to a method for selecting a mutant protein with enhanced displayability over a wild type protein, classified in class 435, subclass 483.
- XVI. Claim 97, drawn to a method of diagnosing a disease in a patient, classified in class 424, subclass 93.2.

It is noted that if Group III is elected applicants need to make a further election of one of the SEQ ID NO:s recited in claim 18. If Group IV is elected applicants need to make a further election of one of the SEQ ID NO:s in each of Claims 41, 56 and 63. These further elections are required because each of the recited SEQ ID NO:s represents a unique, distinct and independent sequence wherein a search of one sequence would not be co-extensive with a search of the others and hence would be burdensome.

The inventions are distinct, each from the other because of the following reasons:

Inventions II, III, IV, V, VII, X, XI and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve yeast cells comprising polypeptides displayed on the cell surface vs. fusion proteins comprising cell wall proteins fused to polypeptides of interest vs. T cell proteins vs. DNA intermediate

products encoding polypeptides of interest vs. gene expression cassettes encoding specific promoters directing expression of DNA molecules encoding fusion proteins vs. soluble T cell receptors vs. T cells with each invention being independent of the others. Each invention does not require the particulars of the other for patentability and each is capable of supporting a separate patent.

Inventions I, IV, VI, VIII, IX, XII, XIV-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve different, distinct methods with each method directed to a distinct, unrelated outcome, i.e. a method of diagnosing a disease in a patient vs. a method for selecting proteins for displayability vs. a method of using high affinity TCRs to identify ligands vs. a method for cloning a gene for a high affinity TCR mutant with each method capable of supporting a separate patent.

Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the T cell product can be made by mutating wild type T cell binding proteins and isolating said proteins.

Inventions XII and XIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

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process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the T cells can be made by isolating the mutant TCRs via display on the surface of yeast cells, cloning said TCRs and expressing them on the surface of T cells.

Inventions VI and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the DNA intermediate products can be made by conventional processes of chemical mutagenesis in host cells which do not involve use of yeast display.

Inventions I, VI, VIII, IX, XII, XIV-XVI (compositions) are unrelated to inventions II-V, VII, X, XI and XIII (methods). Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve compositions vs. methods where each of the methods is not required for generation of each of the claimed compositions and each of the compositions can be made or used independent of the claimed methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
April 18, 2005


DAVID GUZO
PRIMARY EXAMINER